

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants :	Norikazu Ohtake et al.	.	.
Serial No. :	10/561,115	Case No.: BY0026P	. Art Unit:
			. 1624
Filed :	December 15, 2005		. Examiner:
			. Noble E. Jarrell
Patent No :	7,595,316		.
Issued :	September 29, 2009		.
For :	Heteroaryloxy Nitrogenous Saturated Heterocyclic		.
	Derivative		.

Mail Stop: Patent Ext.  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION**  
**OF PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. § 1.705(d)**

Sir:

With reference to the Issue Notification mailed September 9, 2009, the Applicants respectfully request reconsideration of the Patent Term Adjustment for this application under 35 U.S.C. § 154(b).

This Request for Reconsideration of Patent Term Adjustment is being submitted by EFS on November 30, 2009, within 2 months of the issuance of this application as US Patent 7,595,316 on September 29, 2009, or the next business day thereafter, and is accompanied by the fee set forth in 37 C.F.R. § 1.705(b)(1) and § 1.18(e).

Any additional fees associated with this Request may be charged to Merck Deposit Account No. 13-2755.

### REMARKS

The Issue Notification mailed September 9, 2009, indicated that the total patent term adjustment calculated by the Patent Office for this application is 271 days. Applicants hereby respectfully request reconsideration of the patent term adjustment for this application. Specifically, Applicants believe that the total patent term adjustment should be 346 days.

In support of this request, Applicants submit the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

### REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

#### "A Delay"

The Office indicated that the patent term adjustment under 37 C.F.R. § 1.702(a) as calculated under 37 C.F.R. § 1.703(a) is 70 days. The beginning of the relevant period for purposes of calculating "A Delay" is the date on which the application fulfilled the requirements of 35 USC 371. This US national stage application was filed on December 15, 2005, with all of the items required under 35 USC 371. This US national stage application fulfilled the requirements of 35 USC 371 on December 27, 2005, upon expiration of the applicable time limit set forth under PCT Article 39.

A first PTO action was due on or before February 27, 2007 (the date that is fourteen months after the date that the US national stage application fulfilled the requirements of 35 USC 371 on December 27, 2005). The PTO mailed the first Office Action on May 3, 2007, thereby according a PTO Delay of 65 days.

A PTO response to Applicants' response of October 11, 2007, was due on or before February 11, 2008 (the date that is four months after the date of Applicants' response). The PTO mailed the first Office Action on February 21, 2008, thereby according an additional PTO Delay of 10 days.

Applicants response to the Office Action of July 9, 2008, was received by the PTO on October 14, 2008, thereby reducing the period of adjustment under § 1.704(a) by 5 days.

Applicants agree with the determination by the Office that the patent term adjustment under 37 C.F.R. § 1.702(a) as calculated under 37 C.F.R. § 1.703(a) is 70 days.

"B Delay"

Applicants respectfully submit that the patent term adjustment under 37 C.F.R. § 1.702(b) as calculated under 37 C.F.R. § 1.703(b) is 276 days.

The beginning of the relevant period for purposes of calculating "B Delay" is the date on which the application was commenced under the provisions of 35 USC 371(b). The US national stage for this application was commenced on December 27, 2005.

US Patent 7,595,316 granted from the subject application on September 29, 2009. The US national stage for this application was commenced on December 27, 2005. Accordingly, the application should have issued within three years later, on December 27, 2008. However, the actual issue date was September 29, 2009. The difference between the date when the application should have issued to patent on December 27, 2008, and the date that the application actually issued to patent on September 29, 2009, is 276 days.

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:  
February 27, 2007 to February 21, 2008

As detailed above, "B Delay" accumulated during the following period:  
December 27, 2008 to September 29, 2009

The "A Delay" and the "B Delay" overlap (i.e. occur on the same calendar day) for a total of 0 days.

The adjustment sought under 37 C.F.R. § 1.703(f) is the sum of the periods under § 1.702(a) (70 days) and § 1.702(b) (276 days), less the additional delays attributable to Applicant not already included in the periods under § 1.702(a) (0 days), less the days that such periods overlap (0 days). Accordingly, Applicants respectfully request an adjustment of patent term under § 1.703(f) to indicate a total Patent Term Adjustment of 346 days.

In support of Applicants' request for the adjustment under § 1.703(f) to include the sum of the periods under 1.702(a) and § 1.702(b), rather than the greater of these two periods, Applicants rely on the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. September 20, 2008). In that decision, the Court construed the meaning of the statutory provision regarding the limitations on extensions granted for delays under 35 U.S.C. § 154(b)(1)(A-C):

(A) In general. -- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The court stated that “[t]he operative question under 35 U.S.C. § 154(b)(2)(A) is whether periods of delay attributable to grounds specified in paragraph (1) overlap.” See Memorandum Opinion at p. 8. (internal quotations omitted). In the opinion of the district court, “[t]he only way that periods of time can “overlap” is if they occur on the same day.” *Id.* The court thus rejected the Patent Office’s view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) (“A delays”) overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) (“B delay”). In the district court’s view, the only A delays which overlap with the B delay are those which occur after the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application’s filing date, and not before. See Memorandum Opinion at p. 5-6, 9.

Applying the rule in *Dudas* to the present facts, the period for A delays ends on December 27, 2008, which is three years from the filing date of this application, December 27, 2005. The period for B delay begins on December 27, 2008, and ends on the date of issuance of the patent on September 29, 2009, a period of 276 days inclusive. Accordingly, the total patent term adjustment should be calculated from the sum of the non-overlapping A and B periods 70 + 276 - 0 days, less the delays due to applicant during the B period, 0 days, giving a total of 346 days

Terminal Disclaimer

Applicants note that the above-identified application is not subject to a terminal disclaimer.

Applicant Delay

The circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 CFR 1.704 have been noted in the foregoing calculations. Applicants response to the Office Action of July 9, 2008, was received by the PTO on October 14, 2008, thereby reducing the period of adjustment under § 1.704(a) by 5 days.

In that the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas* is under appeal to the Court of Appeals for the Federal Circuit, Applicants respectfully request that any decision on this request for reconsideration of the patent term adjustment be held in abeyance until a final court decision in *Wyeth v. Dudas* is rendered.

In summary, Applicants respectfully requests an adjustment of patent term under 37 C.F.R § 1.703(f) to indicate a total PTA of 346 days. Favorable consideration of this request is earnestly solicited.

Respectfully submitted,

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